

# Impact of the Inflation Reduction Act on Drug Price Negotiations in the United States

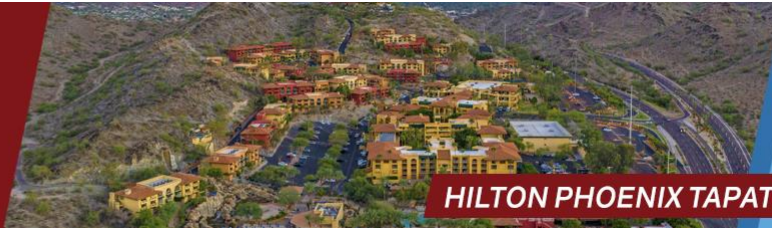
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American  
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**DEVELOPMENTS  
IN PHARMACY LAW  
SEMINAR DPL XXXV**



**NOVEMBER  
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**HILTON PHOENIX TAPATIO CLIFFS RESORT 2024**

# Conflict of Interest Disclosure

- I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.



# Abbreviations and Definitions

- Advisory Committee on Immunizations (ACIP)
- Centers for Medicare and Medicaid Services (CMS)
- Inflation Reduction Act (IRA)
- Affordable Care Act (ACA)



# Learning Objectives

- At the completion of this activity, the participant will be able to:
  - Detail the timeline of the implementation of the Affordable Care Act and the Inflation Reduction Act
  - Describe the risks to the Inflation Reduction Act on further drug price negotiations
  - Determine how medications were chosen for initial price negotiations
  - Describe the future of the IRA and key unanswered questions regarding drug price negotiations



# IRA and Drug Pricing

- First law that allows Medicare to directly negotiate prices of high expenditure, single-source medications without generic or biosimilar equivalents



# Inflation Reduction Act of 2022

- Introduced September 27, 2021 by Rep. John Yarmuth (D-KY)
- Public Law 117-169 August 16, 2022



# Inflation Reduction Act of 2022

- Primarily a climate and energy law
  - Encompasses manufacturing, electrification, home energy retrofit, and new energy technology law
  - Provides tax credits and incentives to encourage job growth and apprenticeships

## The Inflation Reduction Act at Two

Challenges remain, but there's been a lot of progress on restoring an industrial base, creating union jobs, and transforming our energy economy.

BY DAVID DAYEN AUGUST 16, 2024

ENERGY

## How the Inflation Reduction Act sparked a manufacturing and clean energy boom in the U.S.

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# Determining Maximum Fair Price

- The manufacturer-specific factors related to selected drugs include:
  - Research and development costs and the extent to which manufacturer has recouped them
  - Current unit costs of production and distribution
  - Federal financial support for novel therapeutic discovery and development related to the drug
  - Pending and approved patent applications, exclusivities, and certain other applications and approvals
  - Market data and revenue and sales volume data in the US





# Inflation Reduction Act of 2022

- Prescription Drug Pricing Reform
  1. Lowering Prices Through Drug Price Negotiation
  2. Prescription Drug Inflation Rebates
  3. Part D Improvements and Maximum Out-of-Pocket Cap for Medicare Beneficiaries
  4. Continued Delay of Implementation of Prescription Drug Rebate Rule
  5. Miscellaneous



# Inflation Reduction Act of 2022

- 2022
  - ACA
  - Part B increases payments on select biosimilars
  - Rebates required from manufacturers for Part D patients
- 2023
  - Insulin cost sharing capping price at \$35/month
  - Vaccine cost sharing costing patients \$0 for vaccines within ACIP guidelines
  - Rebates additionally required for Part B patients
  - Decreased Part B co-insurance



# Inflation Reduction Act of 2022

- 2024
  - No additional payments in 'catastrophic phase'
  - Premium limits of 6%
  - 'Extra Help' subsidy program for people who earn 150% or more below the federal poverty line
  - July 1, Cap on Part B payments for biosimilars
  - August 16, prices for initial 10 medications finalized



# IRA and Drug Pricing

- Initial 10 Medications
  - 7 taken by >100,000 patients per year
    - Sitagliptin, dapagloflozin, empagloflozin, rivoroxaban, apixaban, sacubitril/valsartan, and various insulins
  - 3 taken by <100,000 patients per year
    - Etanercept, ustekinumab, ibrutinib
  - Cost reduction between 38-79%
- Estimated Part D savings is \$1.5 billion
  - Includes cap of OOP costs



# How Were Medications Chosen

- Each of the 10 medications is:
  - Among the top Medicare drug expenditures
  - Does not have a bona fide generic or biosimilar for any strength or dosage form of a drug product
    - Small Biotech Exception
      - Expenditures under Part D must be 1% or less of total



# Inflation Reduction Act of 2022

- 2025
  - OOP payments NTE \$2000/year for Part D
  - Manufacturer discount program for initial prescriptions and during catastrophic coverage
  - Government coverage during catastrophic phase drops between 40-60%
  - Additional 15 medications announced for price negotiation



# Inflation Reduction Act of 2022

- 2026
  - Negotiated drug prices for 10 initial medications go into effect
  - 15 more meds announced. . .
- 2027-2029
  - Negotiated prices two years prior go into effect
  - 20 more meds announced. . .



# Comparison to International Markets

- US is still paying more than twice international markets
  - Overall pricing
    - 30-day supply of 9/10 drugs is \$17,581 for Medicare in 2026, compared with \$6,725 in Sweden





# Comparison to International Markets

- Imbruvica (Ibrutinib)
  - Medicare price \$9,319
  - Sweden price \$4,607
- Stelara (Ustekinumab)
  - Medicare price \$4,695
  - >4x the cost in Sweden, Australia, and Canada
- Enbrel (etanercept)
  - Medicare price \$2,355
  - Sweden price \$709, Australia \$573, Canada \$704, and Japan \$300



# Comparison to International Markets

- US does get purchasing priority, allowing for early access to new medications and vaccines



# The Future of the IRA

- Remember, this is primarily a climate bill
  - “We’re going to terminate his green new scam,” he said. “And we’re going to end this war on American energy — we’re going to drill, baby, drill.”--Trump



# The Future of the IRA

- U.S. Representative Alexandria Ocasio-Cortez (D-NY) argued that “the public is acting as early investor, putting tons of money into the development of drugs that then become privatized, and then they receive no return on the investment that they have made”



# The Future of the IRA

- Pay twice argument:
  - To what extent is public funding responsible for the invention of most new drugs?
  - Second, are U.S. taxpayers inadequately rewarded for their contribution to new drug development?
  - And third, how are these claims salient to the national debate over drug prices?



# Assessment Questions

The Inflation Reduction Act is primarily an economic and agricultural law, threatening breakdown of drug price negotiations.

- a) True
- b) False



# Assessment Questions

The Inflation Reduction Act puts the US into similar pricing structures as our international counterparts?

- a) True
- b) False



# Selected References

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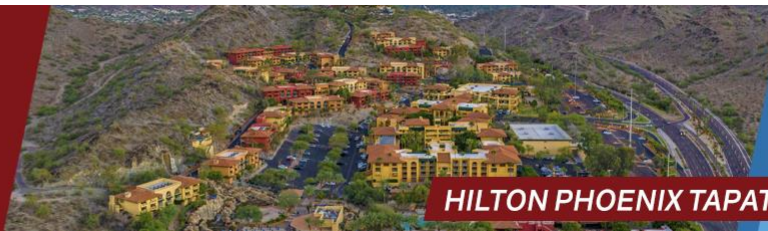
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